

Errata
FDA VRBPAC Briefing Document
GSK CERVARIX
September 9, 2009 VRBPAC Meeting

Page no.	Item	Correction
3	involving ~ 30,000 females 10-55 years of age	involving ~ 30,000 females 10- 72 years of age
4	Antibody titers against both VLP types in 10-15 year old subjects were non-inferior to those in 15-26 year old subjects	Antibody titers against both VLP types in 10- 14 year old subjects were non-inferior to those in 15- 25 year old subjects
5	includes ~ 30,000 females 10-25 years of age	includes ~ 30,000 females 10- 72 years of age
7	A Complete Response letter was sent to GSK on 12/14/09	A Complete Response letter was sent to GSK on 12/14/ 07
7	Table 1 6/26/08 Meeting with CBER and GSK re: discussion of safety and proposal for final efficacy 008	 6/ 24 /08 Meeting with CBER and GSK re: discussion of safety and proposal for final efficacy 008
7	Table 1 10/4/08 Meeting with CBER and GSK re: discussion re: AS04 and MPL	 11 /4/08 Meeting with CBER and GSK re: discussion re: AS04 and MPL

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	Table 2 Study HPV-009 in females 15-25 years of age (naïve and non-naïve)	in females 18-25 years of age (naïve and non-naïve)
8	GSK conducted these clinical studies from 1999-2001	MedImmune conducted these clinical studies from 1999-2001
9	Study sites: This study was conducted by 52 investigators in 12 countries at 57 centers (Australia, Colombia, Czech Republic, France, Germany, Honduras, Korea, Norway, Panama, Spain, Sweden and Taiwan)	Study sites: This study was conducted by 131 principal investigators in 135 centers in 14 countries (Australia, Belgium, Brazil, Canada, Finland, Germany, Italy, Mexico, Philippines, Spain, Taiwan, Thailand, UK and USA) at the time of the final analysis.
14	Table 6: HPV 16 vaccine efficacy 85.7% [82.9, 99.6%]	95.7% [82.9, 99.6%]
24	Peripheral Blood Neutralizing Assay	Pseudovirion Based Neutralization Assay
26	Solicited symptoms and unsolicited symptoms (0-29 days)	Solicited symptoms (0-6 days) and unsolicited symptoms (0-29 days)
28	headache on days of dose 1	headache on day of dose 1
30	See CSR HPV-013 Supplement 19. The incidence of solicited general symptoms reported during the 7-day (Days 0-6) period following each dose and overall did increase with consecutive doses.	The incidence of solicited general symptoms reported during the 7-day (Days 0-6) period following each dose did not increase with consecutive doses.

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33	were provided through 11/17/08, and more recently, through 4/09.	were provided through 11/17/08, and more recently, through 5/17/09 .
34-35	Based on this list (See Attachment 1), a GSK Biologicals physician reviewed the adverse events	Based on this list (See Attachment 1), a blinded GSK Biologicals physician reviewed the adverse events
35	The two most frequently reported NOADs were hypothyroidism, with three subjects in the HPV/[15-25] age group (0.1%)	The two most frequently reported NOADs during the vaccination period were hypothyroidism, with three subjects in the HPV/[15-25] age group (0.1%)
35	The most frequently reported potential autoimmune disease with new onset was hypothyroidism with 22 subjects in the HPV/[15-25] age group (0.2%)	The most frequently reported potential autoimmune disease with new onset over the full observation reporting period was hypothyroidism with 22 subjects in the HPV/[15-25] age group (0.2%)
45	had myelitis; and 26951 (0.03% [95% CI: 0.00, 0.10%]) had optic neuritis	had myelitis; and 2/6951 (0.03% [95% CI: 0.00, 0.10%]) had optic neuritis